(TXR 013599)

(8-3-99)

|Trifloxystrobin | | Prirnary Dermal Juntaiion Study (81-5)

EPA Reviewer: Deborah C. Smegal Toxicology Branch ll(7509C)

EPA Secondary Reviewer: Ching-Hung Hsu, Ph D

Toxicology Branch II (7509C)

IDAi~A EVALUATION RECQifi

STUDY TYPE Primary Dermal Irritation - Rabbit OP~~ 870.2500 [§81-5)

<u>DP BARCODE</u> 243979 <u>P.C. CODE:l291</u> 12 SUBMISSION CODE:5538757 TOX. CHEM. NO.:

TEST MATERIAL (PURITY~: CGA-279202 5OWG-B (50.3% a.i.)

SYNONYMS: Trifloxystrobin formulation

CITATION:

Kuhn, J.O. 1997. Pn mary Dermal Irritation Study in Rabbits. Stulmeadow, Inc. 12852 Park One Drive. Sugar Land, TX 77478. Laboratory Study Number: 3816-97. Novartis Nexus Number 598-97. December 3, 1997. MRID 44496634. Unpublished.

SPONSOR: Novarlis Crop Protection, Inc.

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 44496634), albino New Zealand White rabbits (3/sex) were dermally exposed to 0.5 g of CGA-279202 5OWG-B (50.3% a.i.), moistened with deionized water for 4 hours to 6.25 em² body surface area using a semipermeable dressing. Animals then were observed for 3 days. Irritation was scored by the method of Draize technique.

No edema was observed. Grade I erythema was observed in all animals 1 hour after patch removal, with all signs of erythema subsiding in all animals by 24 hours after patch removal. In this study, CGA-279202 50WG-B formulation is a slight dermal irritant. CGA-279202 50WG-B formulation is classified in TOXICITY CATEGORY IV for primary dermal irritation based on both sexes.

Th~s siudy is classified as acceptable and satisfies the guideline requirement for a primary dermal irritation study (81-5) in the rabbit.

<u>COMPLIANCE</u>: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. Flagging statements were not provided.

NB: This EPA-generated Executive Summary agrees in all major respects with the attached CALEPA's Toxicology Study Evaluation Worksheet summary and conclusions for this study.

SignOff Date: 8/3/99
DP Barcode: D243979
HED DOC Number: 013599
Toxicology Branch: TOX2